

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Jeffrey P. Demuth, et al.

Serial Number: 10/508,932

Filing Date: September 24, 2004

Title: METHOD AND COMPOSITIONS FOR
THE DIAGNOSIS AND TREATMENT OF
NON-SMALL CELL LUNG CANCER
USING GENE EXPRESSION PROFILES

Group Art Unit: 1634

Examiner: Carla J. Myers

CONFIRMATION NO: 9878

FILED ELECTRONICALLY ON: August 13, 2007

Commissioner for Patents
P.O. Box 1450
Alexandria VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97

Sir:

Applicant(s) hereby submit(s) an Information Disclosure Statement along with attached form(s) PTO/SB/08. A copy of each listed publication is submitted, if required, pursuant to 37 CFR §§1.97-1.98, as indicated below.

Applicant(s) respectfully request(s) that the listed information be considered by the Examiner and be made of record in the above-identified application. Applicant(s) further request(s) that the Examiner initial and return the attached form(s) PTO/SB/08 in accordance with MPEP §609.

Applicant(s) reserve(s) the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement is not intended to represent that a search has been made or that the information cited in the statement is, or is considered to be, prior art or material to patentability as defined in §1.56.

- A. ☒ *37 CFR §1.97(b)*. This Information Disclosure Statement should be considered by the Office because:
- ☐ (1) It is being filed within 3 months of the filing date of a national application and is other than a continued prosecution application under §1.53(d);
-- OR --
 - ☐ (2) It is being filed within 3 months of entry of the national stage as set forth in §1.491 in an international application;
-- OR --
 - ☒ (3) It is being filed before the mailing of a first Office action on the merits;
-- OR --
 - ☐ (4) It is being filed before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
- B. ☐ *37 CFR §1.97(c)*. Although this Information Disclosure Statement is being filed after the period specified in *37 CFR §1.97(b)*, above, it is filed before the mailing date of the earlier of (1) a final office action under §1.113, (2) a notice of allowance under §1.311, or (3) an action that otherwise closes prosecution on the merits, this Information Disclosure Statement should be considered because it is accompanied by one of:
- ☐ a statement as specified in §1.97(e) provided concurrently herewith;
-- OR --
 - ☐ a fee of \$180.00 as set forth in §1.17(p) authorized below, enclosed, or included with the payment of other papers filed together with this statement.
- C. ☐ *37 CFR §1.97(d)*. Although this Information Disclosure Statement is being filed after the mailing date of the earlier of (1) a final office action under §1.113 or (2) a notice of allowance under §1.311, it is being filed before payment of the issue fee and should be considered because it is accompanied by:
- i. a statement as specified in §1.97(e);
-- AND --
 - ii. a fee of \$180.00 as set forth in §1.17(p) is authorized below, enclosed, or included with the payment of other papers filed together with this Statement.
- D. ☐ *37 CFR §1.97(e)*. Statement.
- ☐ A statement is provided herewith to satisfy the requirement under *37 CFR §§1.97(c)*;
-- AND/OR --
 - ☐ A statement is provided herewith to satisfy the requirement under *37 CFR §§1.97(d)*;
-- AND/OR --
 - ☐ A copy of a dated communication from a foreign patent office clearly showing that the information disclosure statement is being submitted within 3 months of the filing date on the communication is provided in lieu of a statement under *37 C.F.R. § 1.97(e)(1)* as provided for under MPEP 609.04(b) V.
- E. ☐ *Statement Under 37 C.F.R. §1.704(d)*. Each item of information contained in the information disclosure statement was first cited in a communication from a foreign patent office in a counterpart application that was received by an individual designated in § 1.56(c) not more than thirty (30) days prior to the filing of this information disclosure statement. This statement is made pursuant to the

requirements of 37 C.F.R. §1.704(d) to avoid reduction of the period of adjustment of the patent term for Applicant(s) delay.

F. ☒ 37 CFR §1.98(a)(2). The content of the Information Disclosure Statement is as follows:

☐ Copies of each of the references listed on the attached Form PTO/SB/08 are enclosed herewith.

-- OR --

☒ Copies of U.S. Patent Documents (issued patents and patent publications) listed on the attached Form PTO/SB/08 are NOT enclosed.

-- AND/OR --

☒ Copies of Foreign Patent Documents and/or Non Patent Literature Documents listed on the attached Form PTO/SB/08 are enclosed in accordance with 37 CFR §1.98 (a)(2).

-- AND/OR --

☐ Copies of pending unpublished U.S. patent applications are enclosed in accordance with 37 CFR §1.98(a)(2)(iii).

G. ☐ 37 CFR §1.98(a)(3). The Information Disclosure Statement includes non-English patents and/or references.

☐ Pursuant to 37 CFR §1.98(a)(3)(i), a concise explanation of the relevance of each patent, publication or other information provided that is not in English is provided herewith.

☐ Pursuant to MPEP 609(B), an English language copy of a foreign search report is submitted herewith to satisfy the requirement for a concise explanation where non-English language information is cited in the search report.

-- OR --

☐ A concise explanation of the relevance of each patent, publication or other information provided that is not in English is as follows: _____

☐ Pursuant to 37 CFR §1.98(a)(3)(ii), a copy of a translation, or a portion thereof, of the non-English language reference(s) is provided herewith.

H. ☐ 37 CFR §1.98(d). Copies of patents, publications and pending U.S. patent applications, or other information specified in 37 C.F.R. § 1.98(a) are not provided herewith because:

☐ Pursuant to 37 CFR §1.98(d)(1) the information was previously submitted in an Information Disclosure Statement for another application under which this application claims priority for an earlier effective filing date under 35 U.S.C. 120.

Application in which the information was submitted: _____

Information Disclosure Statement(s) filed on: _____

AND

☐ The information disclosure statement submitted in the earlier application complied with paragraphs (a) through (c) of 37 CFR §1.98.

- I. ☒ *Fee Authorization.* The Commissioner is hereby authorized to charge the above-referenced fees of \$0.00 and charge any additional fees or credit any overpayment associated with this communication to Deposit Account No. 23-2415 (Docket No. 31169-705.831).

Respectfully submitted,

WILSON SONSINI GOODRICH & ROSATI

Dated: August 13, 2007

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By: 

Ray Akhavan, Reg. No. 58,120

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Complete if Known		
			Application Number	10/508,932	
			Filing Date	September 24, 2004	
			First Named Inventor	Jeffrey P. Demuth	
			Art Unit	1634	
Examiner Name	Carla J. Myers				
Sheet	1	Of	3	Attorney Docket Number	31169-705.831

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US 6,001,817	12-14-1999	Shaw	
	2.	US 5,866,617	02-02-1999	Hausheer et al.	
	3.	US 6,229,911	05-08-2001	Balaban et al.	
	4.	US 5,639,606	06-17-1997	Willey	
	5.	US 5,643,765	07-01-1997	Willey	
	6.	US 5,876,978	03-02-1999	Willey	

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁴	
	7.	ALIZADEH, A.A., et al. 2000. Distinct types of diffuse large B-cell lymphoma identified by gene expression profiling. <i>Nature</i> . 403(6769): 503-511.		
	8.	APOSTOLAKOS, M.J., et al. 1993. Measurement of gene expression by multiplex competitive polymerase chain reaction. <i>Anal. Biochem</i> . 213: 277-284.		
	9.	CRAWFORD, E.L., et al. 2000. Normal bronchial epithelial cell expression of glutathione transferase P1, glutathione transferase M3, and glutathione peroxidase is low in subjects with bronchogenic carcinoma. <i>Cancer Res</i> . 60: 1609-1618.		
	10.	CRAWFORD, E.L., et al. 2002. Multiplex standardized RT-PCR for expression analysis of many genes in small clinical samples. <i>Biochemical and Biophysical Research Communications</i> . 293: 509-516.		
	11.	GOLUB, T.R., et al. 1999. Molecular classification of cancer: class discovery and class prediction by gene expression monitoring. <i>Science</i> . 286. 531-537.		

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). *For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. *Scal of document by the appropriate symbols as indicated on the document under: WIPO Standard ST. 16 if possible. *Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet	2	Of	3	Attorney Docket Number	31169-705.831

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁴
	12.	KIHARA, C., et al. 2001. Prediction of sensitivity of esophageal tumors to adjuvant chemotherapy by cDNA microarray analysis of gene-expression profiles. <i>Cancer Res.</i> 61: 6474-6479.	
	13.	PRAKASH, S., et al. 1993. DNA repair genes and proteins of saccharocytes cerevisiae. <i>Annu. Rev. Genet.</i> 27: 33-70.	
	14.	SCHERF, U., et al. 2000. A gene expression database for the molecular pharmacology of cancer. <i>Nat Genet.</i> 24: 236-244	
	15.	WEAVER, et al. 2001. Comparison of expression patterns by microarray and standardized RT-PCR analyses in lung cancer cell lines with varied sensitivity to carboplatin. <i>Proc. Am. Assoc. Cancer Res.</i> 42: 606.	
	16.	WILLEY, J.C., et al. 1997. Quantitative RT-PCR measurement of cytochromes p4a50 1A1, 1B1, and 2B7, microsomal epoxide hydrolase, and NADPH oxidoreductase expression in lung cells of smokers and non-smokers. <i>Am. J. Respir. Cell Mol. Biol.</i> 17: 114-124.	
	17.	ZEMBUTSU, H., et al. 2002. Genome-wide cDNA microarray screening to correlate gene expression profiles with sensitivity of 85 human cancer xenografts to anticancer drugs. <i>Cancer Res.</i> 62: 518-527.	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST. 3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant: Is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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